

510(k) Summary

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Submitted by:

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Product Name:

Proprietary Name:

Affirm One-Step home pregnancy test

Classification Name:

Human chorionic gonadotropin test systems

Intended Use:

Affirm One-Step home pregnancy test is a rapid one-step visual test for the qualitative detection of human chorionic gonadotropin in human urine to aid in the diagnosis of pregnancy. This test is intended for over-the-counter home use.

Description of Device:

Affirm detects the presence of hCG in urine by using a combination of polyclonal and monoclonal antibodies on the reagent pad and the test strip. The assay begins functioning with the addition of urine onto the absorbent wick. Through capillary action the urine is pulled along the membrane to the reagent pad where the hCG reacts with the conjugate. Positive results are determined by one color line in the test window and one color line in the control window. The absence of hCG produces only one color line in the control window.

Predicate device for substantial equivalence comparison:

OneStep Be Sure® Plus Midstream Pregnancy Home Test

Predicate device used as reference test for clinical data:

SAS™ Pregnancy Strip

Date Prepared:

July 19, 1996

Performance characteristics:

Specificity:

Affirm One-Step home pregnancy test was evaluated for specificity against LH, FSH and TSH. At concentrations of 300mIU/ml LH, and 1000mIU/ml FSH and TSH. Affirm did not cross-react with these substances at these levels. Only when Affirm was compared to these three substances and a 25mIU/ml concentration of hCG simultaneously did the tests respond and show a positive reading for the presence of hCG.

Sensitivity and Accuracy:

The sensitivity and accuracy of the Affirm One-Step home pregnancy test was determined using 20 negative urine samples spiked with hCG at varying levels. The following results are described in the table on the following page.

Sensitivity of Affirm One-Step home pregnancy test

Concentration Spiked at:	Results: Positive	Results: Negative
10mIU/ml	5	15
25mIU/ml	20	0
50mIU/ml	20	0
100mIU/ml	20	0
0mIU/ml	0	20

Out of the 20 samples that were tested at the 10mIU/ml concentration, 5 of them did generate a positive reading after about 15 minutes from the point of saturation. The 20 samples tested at the 25mIU/ml concentration all generated a positive reading well within the 20 minutes, therefore our claim is a 25mIU/ml sensitivity with the Affirm One-Step home pregnancy test. Even though the test is sensitive enough to read concentrations lower than 25mIU/ml this does not occur regularly for us to claim a lower sensitivity for the test.

Interfering Substances:

The following potentially interfering substances were added to hCG negative and 25 mIU/ml hCG spiked urine samples. Interfering test samples were compared directly to the control result. The following results are described in the table:

Interference of the Affirm One-Step home pregnancy test

Substance:	Concentration:	Interference:
Acetaminophen	20 mg/dl	NONE
Acetylsalicylic Acid	20 mg/dl	NONE
Ascorbic Acid	20 mg/dl	NONE
Atropine	20 mg/dl	NONE
Caffeine	20 mg/dl	NONE
Gentisic Acid	20 mg/dl	NONE
Glucose	2 mg/dl	NONE
Hemoglobin	200 mg/dl	NONE

Predicate Device Result Correlation:

One hundred specimens were evaluated by the urine stream method and the dip method. The women participating in the study were solicited by a flyer appearing in clinics around town, and asked to participate at one of the following locations: Athena Medical Corporation, Planned Parenthood in either Southeast Portland or Beaverton. Women who participated in the urine stream method answered a questionnaire about the product. Both the Affirm One-Step home pregnancy test and the SAS™ Pregnancy Strip identified 54 true positives and 46 true negatives generating a 100% sensitivity for the Affirm One-Step home pregnancy test.

Substantial Equivalence:

Comparison Product: Be Sure® Plus
Manufactured by: Syntrol Bioresearch Inc.
Carlsbad, CA 92008

Similarities to Be Sure® Plus:

Items to be compared	Affirm One-Step home pregnancy test	Be Sure® Plus
• <u>Detection method:</u>	hCG in urine specimens reacts with the colored-conjugate on the pad producing a solid color (red) line in the test region. Mouse conjugate binds to goat anti-mouse antibody in the control region on the strip.	hCG in urine specimens reacts with the colored-conjugate on the pad producing a solid color (red) line in the test region. Mouse conjugate binds to goat anti-mouse antibody in the control region on the strip.
• <u>Usage:</u>	Anytime of the day.	Anytime of the day.
• <u>Pregnancy determination:</u>	As early as the first day of a women's missed period.	As early as the first day of a women's missed period.
• <u>Antibodies:</u>	Polyclonal goat anti-alpha antibody hCG is on the test strip, monoclonal anti-beta antibody hCG is on the conjugate pad, and polyclonal goat anti-mouse antibody is on the control line.	Polyclonal goat anti-alpha antibody hCG is on the test strip, monoclonal anti-beta antibody hCG is on the conjugate pad, and polyclonal goat anti-mouse antibody is on the control line.
• <u>Results:</u>	Positive = color line in test window and control window. Negative = color line in control window only.	Positive = color line in test window and control window. Negative = color line in control window only.
• <u>Format:</u>	Lateral Flow assay	Lateral Flow assay
• <u>Sensitivity:</u>	Detects level of hCG as low as 25mIU/ml.	Detects level of hCG as low as 25mIU/ml.
• <u>Device design:</u>	Slender, pen-like shape, removable cap, absorbent tip partially enclosed, two window result view.	Slender, pen-like shape, removable cap, absorbent tip partially enclosed, two window result view.
• <u>Visual detection:</u>	A solid color line appears in control and test window in the presence of hCG. A solid color line appears in the control window only in the absence of hCG.	A solid color line appears in control and test window in the presence of hCG. A solid color line appears in the control window only in the absence of hCG.

Differences between Affirm and Be Sure® Plus:

Items to be compared	Affirm One-Step home pregnancy test	Be Sure® Plus
• <u>Device engineering:</u>	Both the result windows and the “tear drops” exposing the absorbent wick appear on the same side of the device. Area covering wick is smaller producing a smaller cap. Result window includes a moisture resistant clear barrier.	Both the result windows and the 2 square windows exposing the absorbent wick are on opposite sides of the device. Area covering the absorbent wick is larger producing a larger cap.
• <u>Developing time:</u>	Less than 4 minutes for the results to appear.	Less than 5 minutes for the results to appear.
• <u>Absorbent wick:</u>	Partially enclosed except for 2 “tear drops” carved out of the plastic housing.	Partially enclosed except for 2 squares cut out of the plastic housing.
• <u>Results windows:</u>	Covered by a clear plastic shield which acts as splash guard to protect the results.	Fully exposed result window with no plastic covering.
• <u>Test window/Control window:</u>	Test window shape is: “+”, control window shape is: “o”.	Test window is a rectangle while the control window is a square.
• <u>Color of holder:</u>	Ivory	Blue/White

The differences between the Affirm One-Step home pregnancy test and Be Sure® Plus are insignificant and do not effect the safety and effectiveness of the device in any significant way.